

**Effective Screening for Pain Study**

**NCT01816763**

**July 2018**

## Analysis plan

1. Describe study eligibility and enrollment.
  - a. Report numbers of patients approached, eligible/ineligible (reasons), enrolled/not enrolled (reasons), and analyzed/not analyzed in standard CONSORT figure (Figure 1)
  - b. Describe characteristics of study sample (numbers, percents, means) by randomized arm (Table 1)
2. Compare study measures
  - a. Describe results of Nurse NRS, NRS-one week assessed via table, PEG, (Table 2):
    - i. Mean (SD) score
    - ii. Percent of scores in no pain (0), mild (1-3), moderate (4-6), and severe (7+) categories.
  - b. Describe agreement on categories of pain severity: weighted kappa statistic for agreement of each screening measure compared with GCPS characteristic pain severity. (Table 3)

## Measure scoring

- 1) Calculate a score for each measure (all 0-10)
  - a) Graded Chronic Pain Scale (GCPS) Characteristic Pain Intensity: Sum of Pain Right Now (Q2) + Worst Pain (Q3) + Usual Pain Intensity (Q4)
    - i) Calculate score as above and divide by 3.
  - b) PEG: Sum 3 items and divide by 3.
  - c) NRS one-week
  - d) NRS nurse
- 2) For all measures, scores are rounded to the nearest whole number and categorized as follows:
  - a) No pain = 0
  - b) Mild pain = 1-3
  - c) Moderate pain = 4-6
  - d) Severe pain  $\geq 7$

**Table 1: Characteristics of randomized participants**

	<b>Arm 1 (nurse NRS) n=</b>	<b>Arm 2 (tablet NRS average) n=</b>	<b>Arm 3 (PEG) n=</b>	
Age, mean (SD) years				
Sex, n (%) male				
Race/ethnicity, n (%)				
White				
Black/African-American				
Asian				
Native American/Alaskan Native				
Native Hawaiian/Pacific Islander				
Hispanic/Latino				

Medical comorbidity score, Seattle mean (SD)				
Physical activity item				
Disability days item				
Depression, n(%) (296.2x, 296.3x, 300.4, 311)				
Anxiety, n(%) (300.0x, 300.2x)				
PTSD, n(%) (309.81)				
Alcohol use disorder, n(%) (303.9x, 305.0x)				
Drug use disorder, n(%) (304.xx, 305.2x-305.7x, 305.9x)				
Back pain (codes TBD)				
Joint pain (codes TBD)				
Headache (codes TBD)				
Neuropathic pain (codes TBD)				

**Table 2: Pain screening outcomes by randomized arm**

	Arm 1 (usual NRS) n=	Arm 2 (tablet NRS average) n=	Arm 3 (PEG) n=		p-value
Screening measure score, mean (SD)					
No pain (0), n (%)					
Mild pain (1-3), n (%)					
Moderate pain (4-6), n (%)					
Severe pain (7+), n (%)					

**Table 3: Agreement of screening measures with reference standard (GCPS characteristic pain intensity) on category of pain severity (none, mild, moderate, or severe)**

	None	Mild	Mod	Severe
Usual NRS				
Tablet NRS average				

PEG				
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